

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**UNITED STATES OF
AMERICA ex rel. LIESA KYER**

Plaintiff-Relator

v.

CASE NO. 2:20-cv-00732

**THOMAS HEALTH SYSTEM, INC.,
HERBERT J. THOMAS MEMORIAL
HOSPITAL ASSOCIATION (d/b/a/
THOMAS MEMORIAL HOSPITAL),
CHARLESTON HOSPITAL, INC. (d/b/a
ST. FRANCIS HOSPITAL),
THS PHYSICIANS PARTNERS, INC.,
and BRIAN ULERY**

Defendants.

**RELATOR'S SUPPLEMENTAL BRIEFING REGARDING *LOPER BRIGHT*
PURSUANT TO ECF 63**

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INTRODUCTION

Relator filed an amended complaint on March 4, 2024 (ECF 52, the “FAC”), alleging, *inter alia*, that physicians who had compensation arrangements with Defendants’ hospitals made referrals for designated health services to those hospitals, and the hospitals submitted claims to government payors for such services, in violation of the Stark Law (42 U.S.C. § 1395nn) and the False Claims Act (31 U.S.C. § 3729, *et seq.*). Defendants moved to dismiss on two grounds: that Relator had not filed her amended complaint under seal and that Relator had filed to satisfy the particularity requirements of Fed. R. Civ. P. 9. (ECF 63 at PageID # 557-58 (discussing Defendants’ motion)). Defendants did not deny that the at-issue physicians made referrals for such services or that claims were submitted for such services, so, as to the Stark Law, the only question for the Court to assess on Defendants’ motion is whether Relator’s amended complaint sufficiently alleges a compensation arrangement between the physicians and the hospitals. *See* ECF 60 at, *e.g.*, PageID # 511 (discussing same and noting “A prima facie Stark Act violation has three elements: (1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for the referred services. This combination of factors suggests potential abuse of Medicare. When they are all present, we let plaintiffs go to discovery.” *U.S. ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 169 (3d Cir. 2019) (citation omitted)).¹ The plain and clear language of the Stark Law, when bumped up against the allegations in the FAC, compels a determination that it does: The Stark Law itself defines “a compensation arrangement” as “*any* arrangement involving *any* remuneration between a physician” and an entity such as Defendants. 42 U.S.C. § 1395nn(h)(1)(A), *emphasis added*. And the FAC plainly alleges that at, *e.g.*, ¶¶ 95-

¹ Relator also properly alleged that Defendants violated the Anti-Kickback Statute (“AKS”), 42 U.S.C. §§ 1320a-7a(a)(7) and 1320a-7b(b). For the reasons set forth in ECF 60, Defendants’ motion as to Relator’s AKS claims should be denied.

122, 123-235. The same answer obtains when the allegations are bumped up against the Stark regulations. As noted in *Bookwalter*, when the Stark Law elements are met, the case proceeds to discovery. 946 F. 3d at 169.

On June 28, 2024, the Supreme Court decided *Loper Bright Enterprises v. Raimondo* 144 S. Ct. 2244 (2024), which overruled *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Because the Stark Law has been fleshed out through regulations, and because *Loper Bright* instructs that this Court not mechanically defer to an agency’s interpretation of the statute, the Court sought briefing on whether certain definitions found in Stark regulations “are consistent with congressional authorization and the statute.” ECF 63 at PageID # 563.

The answer to that question is yes, and, consistent with *Loper Bright* and all of the governing caselaw, the Court can and should deny Defendants’ Motion to Dismiss.

I. The Legal Landscape: *Stark*, *Loper Bright*, and *Skidmore*

A. The Stark Law

“[T]he Stark Law prohibits physicians and entities in financial relationships from improperly benefiting from referrals.” ECF No. 63 at PageID # 558 (citing 42 U.S.C. 1395nn(a)). When a physician and an entity, here Defendants Thomas Health Hospitals, have a financial relationship, “(1) the physician may not make referrals to the entity ‘for the furnishing of designated services for which payment otherwise may be made’ and (2) an entity may not present a claim to a third-party payor ‘furnished pursuant to’ a prohibited referral.” *Id.*; *see also*, FAC at ¶ 21-23. Congress defined a “financial relationship” to include a “compensation arrangement.” 42 U.S.C. 1395nn(a)(2); *see* FAC at ¶ 26. It further defined a “compensation arrangement” as *any* arrangement involving *any* remuneration between a physician and an entity. 42 U.S.C. §

1395nn(h)(1); *see* FAC, ¶ 27-28. Remuneration under the statute includes “any remuneration, *directly or indirectly*, overtly or covertly, in cash or in kind.” *Id.* (emphases supplied)

Additional definitions, as the Court notes, are contained not in the Stark Law but in Stark regulations, promulgated with congressional authority by the agency, the Department of Health & Human Services (“HHS”). As relevant here, those definitions are found at 42 C.F.R. § 411.354(a) (explaining that financial relationships with direct or indirect remuneration results are “direct or indirect compensation arrangement[s]”); 42 C.F.R. § 411.354(c)(1) (defining a “direct compensation arrangement”); 42 C.F.R. § 411.354(c)(2) (defining an “indirect compensation arrangement”); 42 C.F.R. § 411.354(c)(4) (exceptions to indirect compensation arrangements).²

B. The *Loper Bright* Decision

Because *Loper Bright* overruled *Chevron*, it could appear to drastically alter the legal landscape, but the ruling has narrow applicability: Under *Loper Bright*, courts assessing a challenged agency action are no longer *required* to defer to an agency’s permissible interpretation of an ambiguous statute *simply because* the statute is ambiguous. 144 S. Ct. 2244, 2247 (2024). Under *Chevron*, even if a court read an ambiguous statute differently from the agency, if the agency’s interpretation was “permissible,” the court was required to defer. *Id.*, at 2254. In *Loper Bright*, the Court held that the mandatory *Chevron* deference was in conflict with the Administrative Procedure Act (“APA”), which “specifies that courts, not agencies, will decide ‘all relevant questions of law’ arising on review of agency action...even those involving

² The Stark Law is a strict liability statute: A physician is prohibited from making a referral to a hospital for DHS if they have a financial relationship, and the hospital is prohibited from submitting a claim to Medicare or Medicaid for such services, unless that relationship strictly satisfies all requirements of an exception. FAC ¶ 22. The Stark Law provides for several exceptions to the prohibition of referrals for DHS services between physicians and entities that have a financial relationship. *See* 42 U.S.C.S. §§ 1395nn(b)-(e). Congress also delegated to HHS the authority to identify further exceptions by regulation. *See infra*, Section III, A.

ambiguous laws.” *Id.* at 2261. Thus, the Court found, because the mandatory *Chevron* deference could not be squared with the APA, *Chevron* was overruled. *Id.*, at 2273.

That is what *Loper Bright* did. What it did *not* do is equally important, especially here. *Loper Bright* did not do away with regulations writ large, and it neither bound nor vastly expanded the hands of reviewing courts. Nor did it transform, *e.g.*, the use in an FCA complaint of definitions found in regulations into a challenged agency action under the APA. Rather, the claimed mischief wrought by *Chevron* that *Loper Bright* addressed was its insistence “that courts mechanically afford *binding* deference to agency interpretations, including those that have been inconsistent over time.” *Id.*, at 2265 (emphasis in original). *Chevron*, the *Loper Bright* Court noted, “has been a distraction from the question that matters: Does the statute authorize the challenged agency action?” *Id.* at 2252.

Thus, there are key conditions-precident for a court to find itself in *Loper Bright* territory, including that there must be a challenged agency action, and the *statute* (not a regulation) at issue must be ambiguous. More specifically, *Loper Bright* applies when courts are asked to review challenges to an agency’s interpretation of an ambiguous statute that is “‘silent or ambiguous with respect to the specific issue’ at hand.” *Id.* at 2250 (citation omitted). *See also, General Dynamics Land Sys, Inc. v. Cline*, 540 U.S. 581, 600 (2004) (“Even for an agency able to claim all the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent”).

When *Loper Bright* applies, courts are instructed to do as they have always done: interpret the law. *Loper Bright*, 144 S. Ct. at 2248 (citing, *e.g.*, *Decatur v. Paulding*, 39 U.S. 497, 515 (1840)) (observing that “when the meaning of a statute was at issue, the judicial role was to

‘interpret the act of Congress, in order to ascertain the rights of the parties’”). *Loper Bright* plainly does not do away with regulations as a whole, or at all. Nor does it require a court to disagree with an agency’s interpretation of a statute. Indeed, an agency’s interpretation, although no longer binding, may still be especially informative. *Id.* at 2267. And *Loper Bright* instructs courts to give those interpretations “due respect,” while exercising their “independent judgment” to seek out the best meaning of a statute. *Id.* at 2257. While the Court stated that “under the APA [courts] may not defer to an agency interpretation of the law *simply because a statute is ambiguous*,” it did not hold that any court was required to reach a different interpretation than that of an agency—only that mere ambiguity alone was no longer sufficient for agency deference. *Id.* at 2273 (emphasis added). That a court need not reach a different interpretation is particularly so “to the extent [an agency interpretation] rests on factual premises within the agency’s expertise.” *Id.* at 2267 (cleaned up) (citation omitted). “Such expertise has always been one of the factors which may give an Executive Branch interpretation particular ‘power to persuade, if lacking power to control.’” *Id.*, citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). Indeed,

[c]areful attention to the judgment of the Executive Branch may help inform [the court’s] inquiry [into whether an agency has acted within its statutory authority]. And when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it.

Id. at 2273. “The court fulfills that role by recognizing constitutional delegations, fixing the boundaries of the delegated authority, and ensuring the agency has engaged in reasoned decision-making within those boundaries.” *Id.* at 2249 (quotation omitted).

C. *Skidmore* Deference

Long before *Chevron* and even longer before *Loper Bright*, the Supreme Court decided *Skidmore*. 323 U.S. 134. In *Skidmore*, the Court explained that it “has long given considerable

and in some cases decisive weight to [agency] [d]ecisions and to interpretative regulations of the [agency]...” *Id.* at 140 (emphasis added). The court went on to state that, though not controlling, agency interpretations and opinions “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.” *Id.* “The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.” *Id.*

Even as it overruled *Chevron*, the Court in *Loper Bright* underscored *Skidmore*’s continued applicability. *Loper Bright*, 144 S. Ct. at 2262 (“In exercising such [independent] judgment...courts may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes”) (*relying on Skidmore*, 323 U.S. at 140).

Congress delegated authority to HHS to promulgate regulations as needed. That the Stark regulations have been revised over the thirty years since their implementation exemplifies the thorough consideration HHS has given to protect against program or patient abuse as mandated by Congress through the Stark Law. And even with those periodic regulatory revisions, refining what financial relationships are permissible or impermissible, the Stark regulations promulgated by HHS have been consistent in their core prohibition of referrals for DHS services between physicians and entities that have a financial relationship. Accordingly, to the extent the Court needs to look to agency interpretation of the Stark Law, *Skidmore* deference applies. HHS’s regulations applicable to the FAC are well-within the agency’s delegated authority and there is nothing, whether in caselaw, the text of either the statute or the regulations, the history of either, or the plain reading of either, to suggest, let alone conclude, that the at-issue definitions found in the regulations are not the function of reasoned decision-making by the agency.

II. The Court Can Deny Defendants’ Motion Without Implicating *Loper Bright*

A. There is no Challenged Agency Action Here

Neither HHS nor an action by HHS is the subject of the FAC: The FAC challenges not an agency action under the APA, but Defendants’ actions in violation of the FCA. Thus, it would appear that *Loper Bright*, despite its application to agency regulatory schemes generically, would not implicate the Court’s ability to deny Defendants’ Motion to Dismiss in its entirety. *See e.g., Dupree Farms, LLC v. Producers Agric. Ins. Co. (In re Dupree Farms, LLC)*, Nos. 18-00216-5-JNC, 19-00164-5-JNC, 2024 Bankr. LEXIS 1778, at *26 n.10 (Bankr. E.D.N.C. Aug. 1, 2024) (assessing *Loper Bright* to find that while “the limits of an administrative agency’s statutory authority are now a justiciable issue,” the question was not raised—and could not be raised because the agency was “not a party to the action”).

B. The Stark Law is Unambiguous in Text and Purpose

Were the Court to nonetheless find it necessary to assess HHS action here, by virtue of the FAC’s reference to the regulatory framework, *Loper Bright* only comes into play when a *statute* (not regulation) is ambiguous. 144 S. Ct. at 2250-51. “[I]f the intent of Congress is clear, that is the end of the matter.” *Id.* at 2250 (citation omitted). Accordingly, courts are to “reject administrative constructions which are contrary to clear congressional intent.” *Id.* Say what one may about Stark’s myriad regulations (few of which are actually implicated here), the Stark Law is not ambiguous, and congressional intent is plain: Congress enacted the Stark Law to prohibit referrals of DHS services between a physician and an entity if a physician has a financial relationship with an entity, unless an exception applies. 42 U.S.C. § 1395nn(a). Traditional rules of statutory construction, including the text itself, its history, and its purpose, lead only to the conclusion that the Stark Law is unambiguous.

The inquiry begins with the statutory text. *Tanzin v. Tanvir*, 592 U.S. 43, 46 (2020); *Shaiban v. Jaddou*, 97 F.4th 263, 265 (4th Cir. 2024) (same). “‘When a statute includes an explicit definition, we must follow that definition,’ even if it varies from a term’s ordinary meaning.” *Dig. Realty Tr., Inc. v. Somers*, 583 U.S. 149, 160 (2018) (citation omitted). As to the Court’s concern about interpreting the meaning of financial relationship or compensation arrangement, the statute itself provides the definitions: A financial relationship between “a physician...with an entity...is...an ownership or investment interest in the entity, or...a compensation arrangement (as defined in subsection (h)(1)) between the physician...and the entity.” 42 U.S.C. § 1395nn(a)(2). And, a “compensation arrangement” is any arrangement involving any remuneration (*i.e.*, “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind”) between a physician and an entity. 42 U.S.C. § 1395nn(h)(1). Thus, looking at the plain language of the statute, a financial relationship exists where there is *any* arrangement involving *any* remuneration, provided directly or indirectly, between a physician and an entity.³ It cannot be said that the FAC fails to sufficiently allege that Defendants had an arrangement involving remuneration with physicians.⁴

The Court “must read the words Congress enacted ‘in their context and with a view to their place in the overall statutory scheme.’” *Turkiye Halk Bankasi A.S. v. United States*, 598 U.S. 264, 275 (2023) (citation omitted). “And beyond context and structure, the Court often looks to history and purpose to divine the meaning of language.” *Gundy v. United States*, 588 U.S. 128, 141 (2019)

³ That an exception may apply does not alter the definition of financial relationship; if an exception applies, it means only that the financial relationship may be permissible.

⁴ Of course, at trial, Defendants can attempt to show that the evidence does not support the allegations, but on a motion to dismiss, the Court must draw all reasonable inferences from the FAC’s allegations in Relator’s favor. *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999).

(cleaned up) (internal citations omitted). Here, the text of the statute is unambiguously aligned with the overall statutory scheme and the law’s purpose.

The Stark Law was passed to deal with the “problems stem[ming] from the fact a physician’s objectivity in making referrals is threatened by” the physician’s financial interests. 135 Cong. Rec. 2035 (1989). It targeted “referral schemes [that were] being disguised as legitimate business arrangements, most commonly as partnerships involving referring physicians.” *Id.* Based on extensive studying of utilization patterns, Congress determined to *per se* prohibit certain financial relationships and eliminate the effect of financial incentives on referral of patients for designated health services, like the inpatient and outpatient hospital, laboratory, and radiology procedures and services (and DME) at issue here (e.g., FAC ¶¶ 94, 265). *See* 144 Cong. Rec. E4-03 (daily ed. Jan. 27, 1998) (statement of Rep. Stark) (the Stark Law was “designed to reduce or eliminate the incentives for doctors to over-refer patients to services in which the doctor has a financial relationship”). *See also U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 675 F.3d 394, (4th Cir. 2012) (Stark Law “enacted to address overutilization of services by physicians who stood to profit from referring patients to...entities in which they had a financial interest).

Accordingly, the Court need not look beyond the contours of the statute in order to deny Defendants’ Motion to Dismiss, as the Court can assess whether the FAC satisfies Rule 9(b) and whether it should be dismissed for failure to seal it—the only two issues raised in Defendants’ motion—without reference to or reliance on *Loper Bright* or HHS’s interpretation *vel non* of the Stark Law.

C. *Loper Bright* Speaks to Interpretations of Statutes, not Regulations

Loper Bright is concerned with judicial assessment of agency interpretation of *laws*. 144 S. Ct. 2244, 2266 (2024). If a court determines that a *regulation* is ambiguous, however, it must

utilize all traditional tools of construction and judicial interpretation and then follow *Kisor/Auer* deference. *Kisor v. Wilkie*, 588 U.S. 558, 563, 575 (2019) (discussing *Auer v. Robbins*, 519 U. S. 452, (1997)). Under *Kisor*, agencies are afforded deference in *regulatory* interpretations, of genuinely ambiguous regulations, so long as the agency’s reading falls “‘within the bounds of reasonable interpretation.’” *Kisor*, 588 U.S. at 576 (citation omitted); *United States v. Boler*, No. 23-4352, 2024 U.S. App. LEXIS 21379, at *9 (4th Cir. Aug. 23, 2024) (same). To the extent the Court is concerned with ambiguity with the noted regulations, *Kisor* instructs deference to the agency’s reasonable interpretation. This fully supports the Court’s ability to find that the FAC states a claim under the False Claims Act as, *e.g.*, the elements required to show an indirect compensation arrangement readily fall within the bounds of a reasonable interpretation. *See also*, *Bookwalter*, 946 F.3d at 171 (holding complaint satisfied each element).

III. Even if *Loper Bright* Applies, the Implicated Regulations Support Denying Defendants’ Motion to Dismiss

A. The At-Issue Regulations are Well-Within the Agency’s Authority

Should the Court find that the Stark Law is ambiguous, and agency action is being challenged here, *Loper Bright* requires that courts respect the statutory delegation of authority to an agency. 144 S. Ct. at 2273. “When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits...and ensur[e] the agency has engaged in ‘reasoned decision-making’ within those boundaries.” *Id.* at 2263. “[W]here the legislative delegation to an agency on a particular question is implicit rather than explicit, a court may not substitute its own construction of a statutory provision embodying a *reasonable* interpretation of it made by the administrator of an agency.” *Newport News Shipbuilding and Dry Dock Co. v. Garrett*, 6 F.3d 1547, 1557 (Fed. Cir. 1994).

As discussed above, the Stark Law provides clear and broad definitions applicable to the conduct alleged in the FAC, as financial relationship exists where there is *any* arrangement involving *any* remuneration, provided directly or indirectly, between a physician and an entity. Those statutory definitions should be applied broadly. *E.g.*, *Consumer Electronics Ass’n v. FCC*, 347 F.3d 291, 298, 358 U.S. App. D.C. 180 (D.C. Cir. 2003) (Roberts, J.) (“the Supreme Court has consistently instructed that statutes written in broad, sweeping language should be given broad, sweeping application”). In addition, the Stark Law more narrowly specifies several exceptions to compensation arrangement prohibitions, including in the case of physician services provided by physicians within the same practice group, in-office ancillary services, bona-fide employment relationships, and prepaid plans, among others. *See e.g.*, 42 U.S.C. § 1395nn(b)(1)-(3), (e)(2), (h)(1)(C). The statute then specifically, and unambiguously, delegates the authority to HHS to determine other permissible exceptions under 42 U.S.C. § 1395nn(b)(4) and required those exceptions to be specified by regulation through notice and comment rule making.

Accordingly, HHS has the authority to shape the parameters of financial relationships that do not pose a risk of program or patient abuse. This delegation is unambiguous, and under *Gundy* and *Loper Bright* both, the Court must respect such a delegation. *See, e.g.*, *Gundy*, 588 U.S. at 139 (“A delegation is constitutional so long as Congress sets out an intelligible principle to guide the delegatee’s exercise of authority...[a] standard[] [which is] not demanding....Only twice in this country’s history has the Court found a delegation excessive, in each case because ‘Congress had failed to articulate *any* policy or standard’ to confine discretion.”). Put simply, the Stark Law prohibits financial relationships, unless an exception applies—and Congress empowered HHS to establish those exceptions through regulations, which encompass the definitions identified by the Court. Relator’s FAC alleges, with particularity (including specific exemplary false claims), that

Defendants submitted false claims resulting from referrals from physicians with whom they had a financial relationship, and no exception applies.⁵ See e.g., FAC, ¶¶ 2-5, 11-15, 93-122, 125-128, 148-149, 164, 167-235; Appendix A-C. As such, denial of Defendants’ motion is appropriate.

B. Agency Interpretation of the Stark Law is Reasonable and Entitled to Due Respect

Loper Bright instructs courts to give agency interpretations “due respect,” while exercising their “independent judgment” to seek out the best meaning of a statute. 144 S. Ct. at 2257. Agency “expertise has always been one of the factors which may give an Executive Branch interpretation particular ‘power to persuade, if lacking power to control.’” *Id.* at 2267 (citing *Skidmore*, 323 U.S. at 140). “[E]ven in the absence of *Chevron*, courts are well-advised to consider agency “interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time.” *Restaurant Law Ctr. v. U.S. DOL*, No. 23-50562, 2024 U.S. App. LEXIS 21449, at *21 (5th Cir. Aug. 23, 2024) (citing *Loper Bright*, 144 S. Ct. at 2262).

Loper Bright provides guidance on how to exercise that judgment, including that only interpretations “inconsistent with the law” as the court interprets it should be set aside. *Loper Bright*, 144 S. Ct. at 2261. Here, the FAC relies on the Stark Law definition of “compensation arrangement,” defined as “as *any* arrangement involving *any* remuneration between a physician...and an entity.” 42 U.S.C. 1395nn(h)(1) (emphasis added); FAC, ¶ 27-28. Entirely

⁵ The applicability of an exception is an affirmative defense as to which Defendants, not Relator, have the burden of proof. *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 374 (4th Cir. 2015). To the extent the Court finds that HHS regulations regarding Defendants’ purported exceptions are not capable of reasonable application, that would be an issue Defendants would need to overcome at summary judgment; it would not prevent the Court from concluding that the FAC states a claim under the False Claims Act. See, e.g., *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (when the existence of a financial relationship has been established, “the burden shifts to the defendant to establish that the conduct was protected by an exception”); *United States v. Millennium Radiology, Inc.*, 2014 U.S. Dist. LEXIS 138549, *14 fn. 2 (S.D. Ohio Sept. 30, 2014) (safe harbor determination “should be made at the summary judgment stage, or even at trial, and not on a motion to dismiss”).

consistent with that definition, HHS explicated by regulation that “any arrangement” can be either direct or indirect. 42 C.F.R. §§ 411.354(a), (c). Under *Loper Bright*, a court need only consider whether that regulatory definition is consistent with the court’s interpretation of the “best” reading of the statute. Because both “direct” and “indirect” are subsets of “any”, the regulatory definitions certainly do not need the mandatory deference *Chevron* required and survive the typical judicial assessment conducted under *Skidmore*.⁶

Even a brief look at the historical background of the Stark Law and its regulations illustrates that from the outset Congress intended for the agency’s expertise to further implement the prohibition of physician self-referrals under the Stark Law by the promulgation of considered regulations. While changes to those regulations over the last thirty years have refined what financial relationships are permissible or impermissible, they have been consistent in their core prohibition of referrals for DHS services between physicians and entities that have a financial relationship.

The Stark regulations are consistent with the Stark Law. And under *Loper Bright*, due respect to agency interpretation of the Stark Law is “especially warranted when an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time.” 144 S. Ct. at 2258. Such due respect is warranted to HHS’s interpretation of the Stark Law as it relates to the definitions noted by the Court.

⁶ Further, “interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute’s meaning.” *Loper Bright*, 144 S. Ct. at 2262. Here, that the Stark regulations were contemporaneous to the Stark Law supports their utility in determining the statute’s meaning. *See generally*, Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1663 (1998) (describing self-referral prohibition and exceptions to the prohibition regulations implemented as early as December 3, 1991).

C. *Loper Bright* is not Retroactive and Does not Overrule Prior Cases Utilizing *Chevron* Deference

The *Loper Bright* decision does “not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful...are still subject to statutory *stare decisis*...” 144 S. Ct. at 2273. As the Sixth Circuit recently noted, “while *Loper Bright* opens the door to new challenges based on *new* agency actions interpreting statutes, it forecloses new challenges based on specific agency actions that were already resolved via *Chevron* deference analysis.” *Tennessee v. Becerra*, No. 24-5220, 2024 U.S. App. LEXIS 21521, at *21 (6th Cir. Aug. 26, 2024) (emphasis in the original). The Stark Law and regulations applicable to the FAC pre-date *Loper Bright*, and are not new agency actions. Thus, cases, including those referenced by the Court, that have discussed the *Chevron* framework in relation to the Stark Law are subject to *stare decisis*, and support that the Court may permissibly rely on the rationale of those cases if needed to reach its ruling on Defendants’ motion.

1. *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*, 675 F.3d 394, (4th Cir. 2012)

First, before it got to *Chevron*, the *Drakeford* court had no trouble framing the issue before it by reference to both the Stark Law and its regulations, including, *e.g.*, that “[t]he Stark Law and Stark Regulations define a ‘financial relationship’ to include ‘a compensation arrangement’ in which ‘remuneration’ is paid by a hospital to a referring physician ‘directly or indirectly, overtly or covertly, in cash or in kind’” and then proceeding to explain, with citation to the regulations, what an “indirect” financial relationship is. *Drakeford*, 675 F.3d at 398. After resolving the issue presented, the Fourth Circuit provided guidance to the district court on remand. Specifically, the Circuit addressed what constitutes a “referral” under the Stark Law. *Id.* at 407. Again applying both the Stark Law and Stark regulations “as interpreted by the agency,” it determined a “referral” existed in that matter. *Id.* There, it did note the *Chevron* framework because it found that Congress

had not spoken directly on “the issue of whether a facility component constitutes a referral.” *Id.* at 407 n.21. The court found the agency’s interpretation was “eminently reasonable,” and noted that such deference to the agency’s interpretation was due because “the agency possesses special expertise in interpreting the Stark Law, the interpretation emerged out of notice-and-comment rulemaking, and involved a statute of sufficient complexity that it was fair to assume that Congress understood that the agency would be required to engage in policy making when it administered the statute.” *Id.* Nothing in *Loper Bright* challenges *Drakeford* at all, and *Drakeford* remains authoritative here.

2. *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015)

Burwell was brought under the APA, with a physician association challenging HHS’s authority to issue certain regulations regarding leases. *Burwell*, 790 F.3d 212, 214. As such, the court relied on the *Chevron* framework to determine whether HHS’s construction was reasonable. *Id.* at 219. Notably, part of the defendant’s challenge to the new regulations was under the APA, the very statute addressed in *Loper Bright*.⁷ *Id.* at 224. In relevant part, the court determined that “[t]he Stark Law gives the Secretary power to add requirements ‘as needed to protect against program or patient abuse,’ even if Congress did not anticipate such abuses at the time of enactment.” *Id.* at 220. Further, the court found that “[t]he Secretary’s regulation redefining an ‘entity furnishing designated health services’ [was] a reasonable construction of the statute that [was] entitled to [*Chevron*] deference.” *Id.* at 226. As a part of its analysis in reaching that conclusion, the court relied on 42 U.S.C. § 1395nn(h)(1)(A) (defining a compensation arrangement

⁷ *Burwell* is distinguishable from the matter at hand because it involved agency action and the agency was a party to the action. There is no such agency action before the Court in this matter, nor is the agency a party named in the FAC. *See supra, Dupree Farms*, 2024 Bankr. LEXIS 1778, at *26 n.10,

as “any arrangement involving any remuneration between a physician...and an entity”), and the corresponding regulation at 42 C.F.R. § 411.354(a)(2) (defining financial relationship to include both direct and indirect financial relationships), as exemplifying a permissible, and meaningful, construction of the Stark Law that was entitled to deference. *Id.* at 224-225.

3. *U.S. ex rel. Villafane v. Solinger*, 457 F. Supp. 2d 743 (W.D. Ky. 2006)

Part of the question before the court in *Villafane* was whether the defendants’ financial relationship fell under the Academic Medical Center (“AMC”) exception to the Stark Law. *Villafane*, 457 F. Supp. at 756. Notably, the court found that “[s]ince the AMC exception is contained in the Code of Federal Regulations...the regulation serves as an administrative interpretation of the meaning Congress intended when creating the statute.” *Id.* In short, the court found that the Stark Law delegated authority to HHS to establish additional exceptions through regulation, and the agency had properly done so. *Id.* at 756-57. In making that determination, the court cited *Chevron* but conducted its own analysis, including looking at the statutory language (42 U.S.C. § 1395nn(e)(7)) and the legislative history (66 Fed. Reg. 856, 916 (Jan, 4, 2001)), to determine that “the regulations defining the scope of the AMC exception to the Stark law constitute a reasonable and permissible construction of the statute.” *Id.* The court went on to hold that it was the defendants’ burden to prove they met the requirements for the exception. *Id.* at 757.

Each of these matters employed the *Chevron* framework in interpreting the Stark Law, *Loper Bright* did not upend them, and in the case of *Tuomey*, it remains controlling authority.

Further, previous judicial decisions confirm that the Stark regulations are consistent with the Stark Law and provide additional guidance for the Court in exercising its independent judgment. *See, e.g., Tuomey*, 792 F.3d at 377 (assessing both law and regulations and finding claims were false because they violated the Stark Law); *Bookwalter*, 946 F.3d 162 (assessing both

law and regulations and holding the operative complaint alleged facts sufficient to make out a Stark claim, including that an indirect compensation arrangement existed, and that any Stark exceptions were defendants' burden to prove); *Kosenske*, 554 F.3d at 96 (after considering both the law and the regulations, holding that financial arrangement implicated Stark Law and defendant failed to meet its burden to show its right to an exception); *U.S. ex rel. Fischer v. Cmty. Health Network, Inc.*, 2021 U.S. Dist. LEXIS 271155, at *8, 26-27 (S.D. Ind. Oct. 20, 2021) (assessing both law and regulations and upholding complaint alleging that "physician compensation arrangement for the different specialty groups exceeded fair market value compared to various benchmarks"); *U.S. ex rel. Emanuele v. Medicor Assocs.*, No. 10-245, 2017 U.S. Dist. LEXIS 136637 (W.D. Pa. Aug. 25, 2017) (assessing both law and regulations finding defendants' violations of the Stark Law and the AKS were material under the FCA).

Relator's FAC alleges, with particularity (including specific exemplary false claims), that Defendants submitted false claims arising from an arrangement involving remuneration, provided directly or indirectly, between physicians and Defendants and that no exception applies. More granularly, it sets forth allegations supporting that the physicians and Defendants had a direct compensation arrangement (which is plainly a subset of "any") because, e.g., the various entities within the Thomas Health System functioned as a single entity, and the physician employment contracts with Defendant "specify that the *Thomas Health Hospitals* desire to provide employment to the physician. ECF 60 at PageID #512, discussing same and referencing FAC ¶¶ 95-122. The FAC also supports with detail how the Court could find that the compensation arrangement was indirect (plainly encompassed within *any* remuneration provided *directly* or *indirectly*), as it provides detailed allegations of an unbroken chain between THSPP and Thomas Health Hospitals, that the aggregate compensation paid to physicians varies with the volume or value of referrals,

and that Thomas Health Hospitals had knowledge of the physicians' compensation arrangements. FAC, at ¶¶ 123-235; *see Bookwalter* 946 F.3d at 170-71 (describing elements of an indirect compensation arrangement).

CONCLUSION

“The Stark Law is intended to prevent physicians' financial interests from affecting whether they refer patients for outpatient procedures and where the patient is referred.” *Burwell*, 790 F.3d at 225. The Stark Law prohibits referrals from a physician to a hospital with which the physician has a financial relationship—*any* arrangement involving *any* remuneration between a physician and an entity—and the FAC plausibly alleges in detail how Defendants' have such a relationship, whether direct or indirect—i.e., “any” arrangement. *See e.g.*, FAC at ¶¶ 95-122; ¶¶ 123-235. In their Motion to Dismiss, Defendants do not deny that the physicians at issue made referrals to the Thomas Health Hospitals for DHS, and that the hospitals submitted claims for such services—nor could they, as the FAC includes specific examples of such claims, and Defendants do not challenge the sufficiency of these allegations.

The Stark Law is unambiguous, and the Stark regulatory scheme is consistent both with the power given the agency by Congress and the Stark Law itself. Based on the plain language of the Law, the explicit delegation of authority by Congress to HHS, the deference owed the agency under *Skidmore*, previous caselaw, and the Court's employment of its independent judgment, the Court should find that the FAC properly alleges that Defendants submitted false claims that were rendered false because of they were submitted by an entity with which the referring physicians had a financial relationship in violation of the Stark Law and the False Claims Act. The FAC details with particularity each of the statutory elements and provides sufficient basis for the Court to deny Defendants' motion.

For all of the foregoing reasons and those contained in Relator's opposition to Defendants' motion, the Court should deny Defendants' Motion to Dismiss in its entirety.

Respectfully submitted,

/s/ Letitia Neese Chafin

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing will be served via the Court's electronic filing system and served on all counsel of record on this 4th day of October 2024.

/s/ Letitia Neese Chafin
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